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|---|-------------|----------------------|--------------------------------------|------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.                  | CONFIRMATION NO. |
| 10/625,164  | 07/23/2003  | Eddie Reed           | 27497/2002                           | 8006             |
| 29932 7590 04/03/2007<br>SONNENSCHN NATH & ROSENTHAL LLP<br>FOR PAULA EVANS<br>P.O. BOX 061080<br>WACKER DRIVE STATION, SEARS TOWER<br>CHICAGO, IL 60606-1080 |             |                      | EXAMINER<br>HOEKSTRA, JEFFREY GERBEN |                  |
|   |             |                      | ART UNIT                             | PAPER NUMBER     |
|   |             |                      | 3736                                 |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE                        |                  |
| 3 MONTHS  |             | 04/03/2007           | PAPER                                |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/625,164             | REED ET AL.         |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Jeffrey G. Hoekstra    | 3736                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 8-34 is/are pending in the application.
- 4a) Of the above claim(s) 8-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 04/19/2006, canceled claim(s) 1-8, and new claim(s) 9-34 is/are acknowledged. The current rejections of the claim(s) 1-8 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

### ***Election/Restrictions***

2. Applicant's election with traverse of Group III in the reply filed on 01/12/2007 is acknowledged. The traversal is on the ground(s) that it would not be an undue burden to examine the claims of Group I and Group II with the claims of Group III. This is not found persuasive because as broadly as structurally claimed Groups I and II may be used for materially different processes as recited in the previous Office Action.

The requirement is still deemed proper and is therefore made FINAL.

3. Applicant's election with traverse of Species B in the reply filed on 01/12/2007 is acknowledged. The traversal is on the ground(s) that both Species A and B encompass polypeptide detection. This is found persuasive and the Election of Species requirement is withdrawn.

4. Claims 8-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 01/12/2007.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. This application contains claims 8-24 drawn to an invention nonelected with traverse in Paper No. 20070112. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Drawings***

7. The drawings were received on 04/19/2006. These drawings are *--not acceptable--*.

8. The drawings are objected to because they appear to be copies of color photographs (see paragraph 9) and they are illegible informal images. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

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made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

9. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

### ***Specification***

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

### ***Claim Objections***

11. Claim 25 is objected to because of the following informalities: the claim does not appear to be a complete sentence as it is lacking the positive recitation of "and" between steps (a) and (b). Appropriate correction is required.

12. Claim 34 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim --*should refer to other claims in the alternative only*--. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

### ***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 25-27 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Fournier (US 6,155,990) as broadly as claimed.

15. Fournier discloses a method for detecting human papilloma virus (HPV) in a vaginal specimen by obtaining a vaginal specimen containing few endocervical cells and using a DNA probe to detect the presence of HPV (column 2 line 65), said method comprising:

- obtaining said vaginal specimen using a device comprising a collection element (as best seen in Figures 1-3) comprising an inner tube (4) and a brush (2) attached to

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said inner tube, and an outer tube (1) or shield surrounding said collection element and

- detecting the presence of HPV in said vaginal specimen via microbiologic assay (column 3, line 3).

### ***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fournier in view of Zavada et al (2003/0049828). Fournier discloses the claimed invention except for explicitly disclosing specimen testing including (a) extracting DNA and amplifying HPV nucleic acid to detect the presence of HPV and (b) contacting the

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specimen with a multiple polypeptides that bind to a HPV antibody or protein and subsequent detection of the bound antibody or protein in the specimen. Zavada et al teaches specimen testing including (a) extracting DNA and amplifying HPV nucleic acid (paragraphs 33-34) to detect the presence of HPV and (b) contacting the specimen with a multiple polypeptides that bind to a HPV antibody (paragraph 35) or protein (paragraph 40) and subsequent detection of HPV (paragraph 17) in the specimen. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as taught by Fournier, with the method as taught by Zavada et al for the purpose of increasing the detection of HPV screening by detecting cervical cancerous conditions using antibody and protein binding and detection.

### ***Response to Arguments***

19. Applicant's arguments with respect to claims 25-34 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JH

*Max F. Hindenburg*  
Max F. Hindenburg  
Supervisor